

REMARKS

Upon entry of the foregoing amendment, Claims 92, 94, 96, 98-101, 105, 106 and 109 will remain pending in the application. Claims 92, 100, and 109 have been amended. Claims 96 and 115-19 have been canceled. These changes do not introduce new matter. Allowance of all pending claims in view of the following remarks is respectfully requested.

In the Office Action of February 19, 2004, the Examiner set forth a number of grounds for objection and rejection. These grounds are addressed individually and in detail below.

Rejections under 35 U.S.C. § 112, first paragraph

Written Description

Claims 92, 94, 96, 98-101, 105, 106, 109 and 115-119 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement for the reasons set forth on pages 2-4 of the Office Action. Applicants respectfully traverse the rejection.

With respect to Claims 92, 94, 96, 98 and 99, the Examiner alleges that the specification fails to support the combination of the bGH pA with any constitutive promoter other than the promoter disclosed in the Examples. Applicants respectively submit that the ground of objection has been obviated by the amended Claim 92, which recites only the MFG promoter and is supported by Figure 6 of the specification. Accordingly, withdrawal of the rejection to Claims 92, 94, 96, 98 and 99 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

With respect to Claims 100, 101, 105, 106 and 109, the Applicants have amended independent Claims 100 and 109 to recite the MuLV IVS and env ATG between the MFG promoter and fIX coding sequence. As indicated by the Examiner, this amendment would obviate the rejection to these claims. Withdrawal of the rejection to Claims 100, 101, 105, 106 and 109 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 115-119 have been canceled by this amendment. Rejections to these claims are now moot.

Enablement

Claims 92, 94, 96, 98-101, 105, 106, and 109 stand rejected under 35 U.S.C. §112, first paragraph, for lack of enablement for the reasons set forth on pages 4-5 of the outstanding Office Action. The Examiner indicates that the Claims 92-114 are enabled only to those embodiments shown in the specification, such as the rAAV consists of terminal repeats flanking in order an MFG promoter, adjacent MLV intervening sequence including the splice donor and acceptor sites and env ATG, a Factor IX coding sequence, and bovine growth hormone poly A sequence.

In order to expedite prosecution, Applicants have amended independent Claim 92 to recite only the MFG promoter, and amended independent Claims 100 and 109 to recite the MuLV IVS and env ATG between the MFG promoter and fIX coding sequence.

Taken together, it is believed that this ground of rejection has been obviated, and therefore, the rejection under 35 U.S.C. § 112 first paragraph should be withdrawn.

Allowable Subject Matter

Applicants thank the Examiner for the indicating that Claims 100, 101, 105, 106, and 109 would be allowable if the MuLV IVS and env ATG are included in the claims. Applicants have complied with the Examiner's suggestion and have amended independent Claims 100, and 109 to be allowable.

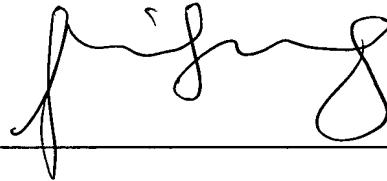
CONCLUSION

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to contact Ping Wang, M.D. (Reg. No. 48,328) at the telephone number listed below.

Respectfully submitted,

PIPER RUDNICK LLP

A handwritten signature in black ink, appearing to read 'S. Kelber', is written over a horizontal line.

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